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**GAIT ANALYSIS SYSTEM AND METHODS****CROSS REFERENCE TO RELATED APPLICATION**

This application is a divisional of application Ser. No. 14/097,903, filed Dec. 5, 2013, which is a divisional of application Ser. No. 12/851,614, filed Aug. 6, 2010, now U.S. Pat. No. 8,628,485, which applications are incorporated herein by reference in their entirety.

**TECHNICAL FIELD**

This application relates to a system and methods for collecting, calculating and outputting data useful in analyzing the gait of an individual.

**BACKGROUND**

Disorders of asymmetries and/or imbalances in gait have been associated with significant clinical morbidity, mortality, and healthcare cost and resource utilization. For example, loss of balance and falls can result in acute injuries, hospitalization, and deaths. Additionally, the progressive deterioration of the joints, either with associated pain or without pain, can cause balance/gait disorders. For example, injuries to the anterior cruciate ligament can lead to deterioration of the knee joint anatomy and function. Another example is the deterioration at the knee or hip joint anatomy and function secondary to rheumatoid arthritis and/or osteoarthritis, either before or after partial or total hip joint replacement surgery. Yet another cause of balance/gait disorders is unequal weight bearing between the lower extremities, resulting in chronic musculoskeletal pain, including back pain. As might be appreciated, numerous challenges exist in preventing, treating and rehabilitating balance and gait disorders.

Even though the causes for many balance and gait disorders are well understood, improvements in assessment tools for analyzing these disorders are desired. This is particularly the case where it is desired to assess gait and/or balance quantitatively during the totality of ambulation and activity over a prolonged period, for example, over the course of a full day.

**SUMMARY**

Systems and methods for analyzing the gait of an individual are disclosed. In one method, data are acquired from a first array and a second array of pressure sensors and/or shear stress sensors that are configured to be placed in a left and right shoe, respectively. By the use of the term "shoe" it is broadly intended to mean any foot appliance suitable for fitting sensors that will be on or near an individual's foot. By way of non-limiting examples, a shoe can be a walking shoe, a dress shoe, a running shoe, a sandal, a slipper, or a foot appliance designed for the specific purpose of assessing a person's gait. The acquired data are collected or separated into at least two separate gait phases for each array and then compared to a baseline condition for each gait phase. The pressure sensors in the array are then categorized into one of at least two pressure uniformity categories for each gait phase based on the results of the comparison of the acquired data to the baseline condition. A graphical output showing at least one entire gait cycle based on the pressure uniformity categories can then be generated. An additional graphical output showing shear stress and resultant torque values can be overlaid onto the graphical output showing the pressure unifor-

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mity categories. It should also be noted that the system can be used to evaluate a single foot of an individual, or can be used to evaluate both feet.

In another method, data are acquired onto a computerized storage device, transformed into a data evaluation set and analyzed. The acquired data can comprise pressure and time information from a first array of pressure sensors disposed in a left shoe and a second array of pressure sensors disposed in a right shoe wherein each pressure sensor in the first array having a corresponding and similarly located pressure sensor in the second array that together form a pressure sensor pair. The data evaluation set can be created by parsing at least some of the acquired data into at least two separate gait phases for each array, calculating a mean pressure value for each sensor for each similar gait phase, and calculating a mean pressure value for each sensor pair for each similar gait phase. The data can be analyzed by comparing, for each gait phase, the mean pressure value for each sensor to the sensor pair mean pressure value and to a mean pressure deviation limit value, and categorizing each sensor into one of at least two pressure uniformity categories for each gait phase on the basis of the comparison. Instead of, or in addition to, using mean data, median data may also be used. The method can also comprise creating a graphical output based on the category into which each sensor has been placed wherein the output shows at least one entire gait cycle wherein each gait phase is individually represented by a right footprint and/or a left footprint. Additionally, the graphical output can show shaded, patterned or colored areas correlating to the pressure uniformity category for each pressure sensor on each footprint for each gait phase in the gait cycle wherein the shaded, patterned or colored areas are shown on each footprint at a location corresponding to the actual sensor location within the shoe. Examples of patterns include, among many others, hatching and repeated use of pre-defined symbols or shapes.

In one exemplary system, a first array of pressure and/or shear stress sensors is configured to be positioned in a left shoe and a first data transmitter is configured to transmit stress, pressure and time data from the first array of pressure and/or shear stress sensors to a data collection device. A second array of pressure and/or shear stress sensors is also configured to be positioned in a right shoe and a second data transmitter is configured to transmit stress, pressure and time data from the second array of pressure and/or shear stress sensors to a data collection device. A data collection device can also be part of the system to receive data from the first and second transmitters.

The system can also include a computer processor constructed and configured to: compare, for at least two separate gait phases, at least a portion of the acquired data to a baseline condition; and to categorize the pressure sensors in each array, or a group of pressure sensors in each array, into one of at least two pressure uniformity categories for each gait phase based on the comparison of the acquired data to the baseline condition. The computer processor can also be constructed and configured to: calculate a mean and/or median pressure value for each sensor for each similar gait phase; calculate a mean and/or median pressure value for each sensor pair for each similar gait phase; compare, for each gait phase, the mean and/or median pressure value for each sensor to the sensor pair mean pressure value and to a mean and/or median pressure deviation limit value; and categorize each sensor into one of at least two pressure uniformity categories for each gait phase on the basis of the comparison of the sensor to the sensor pair.

The disclosed gait analysis system is specifically at least able to record the following parameters while the individual is